

DSJ1&2-PR Exh 597

Garlitz, Margaret A.

From: Grail, Efrem M.
Sent: Thursday, June 07, 2007 6:15 PM
To: Garlitz, Margaret A.
Subject: FW: AmerisourceBergen -- DEA

Attachments: Letter to Hon Dianne Feinstein.pdf; Form of letter to DEA administrator v3.DOC

copies

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From: Chou, John [mailto:jchou@amerisourcebergen.com]
Sent: Thursday, June 07, 2007 5:22 PM
To: Peter_Cleveland@feinstein.senate.gov
Cc: Norton, Rita; Frederick Graefe
Subject: AmerisourceBergen -- DEA

Peter:

As a followup to our meeting last week, I have attached for Senator Feinstein's consideration a letter from AmerisourceBergen that seeks her assistance in encouraging the Drug Enforcement Administration ("DEA") to agree to meet with AmerisourceBergen and move expeditiously in its interactions with AmerisourceBergen regarding the suspension of the DEA registration of AmerisourceBergen's Orlando distribution center. We hope that Senator Feinstein will consider it appropriate and justified to send a letter to DEA Administrator Karen Tandy for this purpose.

For Senator Feinstein's consideration and convenience, we have provided a form of letter that she might use in communicating with DEA Administrator Tandy. The form of letter is contained as an attachment to the letter from AmerisourceBergen to Senator Feinstein. The letter to Senator Feinstein, with attachments, is attached as a pdf document to this email. For your convenience, I also have attached a Word version of the form of letter to DEA Administrator Tandy, should Senator Feinstein wish to use our form of letter as a starting point for any communication with the DEA.

Please contact me if you have any questions about the attached letter or if there is any information that you would like us to provide.

Thank you for your assistance on this matter. As you know from our discussions last week, time is of the essence for AmerisourceBergen and any help that we can obtain to accelerate our dealings with the DEA will be greatly appreciated.

Regards,

John

John Chou
Senior Vice President, General Counsel and Secretary
AmerisourceBergen Corporation

06/08/2007

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June 7, 2007

The Honorable Dianne Feinstein
United States Senate
331 Hart Senate Building
Washington, DC 20510

Dear Senator Feinstein:

I am writing to you on behalf of AmerisourceBergen Corporation. With more than \$64 billion in annual revenue, AmerisourceBergen is one of the largest pharmaceutical services companies in the United States, providing drug distribution and related services for pharmaceutical manufacturers and healthcare providers. AmerisourceBergen's service solutions range from pharmacy automation and pharmaceutical packaging to pharmacy services for skilled nursing and assisted living facilities, reimbursement and pharmaceutical consulting services, and physician education. AmerisourceBergen Drug Corporation ("ABDC"), a subsidiary, distributes approximately 30% of all of the drugs dispensed in the United States to thousands of hospitals, other healthcare providers and pharmacies. These healthcare providers, hospitals and pharmacies rely on AmerisourceBergen to carry all of the products they need to dispense to patients and to deliver the products on a just-in-time basis. AmerisourceBergen employs more than 800 associates at three major pharmaceutical distribution centers in California and has several other smaller facilities in California as well.

On April 24, 2007, the Drug Enforcement Administration (the "DEA") commenced an administrative proceeding against our distribution center in Orlando, Florida (the "Orlando Facility"). Specifically, without advance notice, the DEA suspended the Orlando Facility's registration to distribute controlled substances to pharmacies based on allegations that AmerisourceBergen distributed hydrocodone to four DEA-registered pharmacies that, according to DEA, AmerisourceBergen should have known were using the Internet to engage in improper diversion of the drugs. Notably, two of the four pharmacies listed by DEA still hold valid DEA registrations to purchase and dispense controlled substances. AmerisourceBergen has substantial legal and factual defenses to the allegations.

As you know from the letter sent to you on May 22, 2007, from our CEO David Yost, we support the Online Pharmacy Consumer Protection Act of 2007 and the elimination of

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illicit Internet pharmacies. We believe that the legislation you have sponsored is critical because the current law does not provide distributors like us with any standard by which to determine which pharmacies are engaged in improper activities and which pharmacies are engaged in lawful activities. In addition, DEA has failed to provide any clear objective standards or other regulatory-type guidance to assist us as we try to help DEA accomplish its mission. Because of the lack of clarity in the law, the absence of other guidance and for other reasons, we believe that the action taken by the DEA against us, without warning or notice, is unjustified and unwarranted. Historically, we have been a company that has worked very closely with DEA and has always cooperated with DEA. Attachment 1 to this letter summarizes some of the cooperation and collaboration between AmerisourceBergen and the DEA. You will see, among other things, that AmerisourceBergen assisted the DEA on the Operation Cyber Rx (Johar Saran) case of which the DEA is so rightfully proud.

We are suffering significant economic harm from the DEA's arbitrary and unjustified action. We have incurred \$2.5 to \$3 million in expenses alone since April 24, 2007. For example, we have had to pay \$100,000 in UPS charges per week to supply necessary medicine to our validly DEA-registered customers in Florida from a distribution center in Columbus, Ohio. We also anticipate losing a significant portion of our business in Florida as our competitors take advantage of the DEA action and our resulting inability to ship to our customers from Florida. Notwithstanding our substantial efforts at our expense to assist DEA as described in Attachment 1, we are being portrayed publicly by DEA in this action as part of the problem, when the truth is that we have been and will continue to be part of the solution. We believe that none of our competitors has suspicious order monitoring and customer verification practices that are as stringent as ours.

Although we believe that we would be able to successfully defend ourselves against the DEA's allegations if we were willing to engage in a long and lengthy legal battle, we also believe that the most responsible course of action for us, our stockholders and the public is to try to settle this matter with the DEA in a manner that creates a win-win for the DEA and the industry by implementing additional anti-diversion procedures at AmerisourceBergen that the DEA can hold as a standard for all distributors to follow.

We have tried to engage the DEA in settlement discussions since April 24, 2007, and successfully arranged a number of meetings that were convened between April 25 and mid-May. At those meetings, the DEA indicated its satisfaction with the numerous enhanced anti-diversion procedures that we have implemented in Florida and are willing to implement at all of our 26 distribution centers across the country. But rather than engage in any further substantive negotiations, on May 25, DEA declared that regardless of such enhanced procedures, the Orlando Facility would remain closed until August 25,

The Honorable Dianne Feinstein
June 7, 2007
Page 3

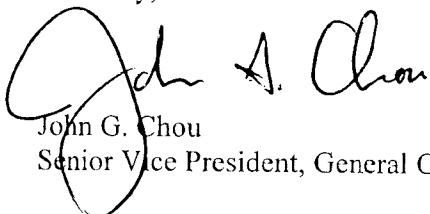
2007, a clearly punitive measure. We formally submitted a detailed counteroffer to DEA on May 29, 2007, but were advised yesterday that our counteroffer was rejected in its entirety.

Most significantly, the DEA rejected our request for a face-to-face meeting to discuss our counterproposal and the DEA's position. We believe that a face-to-face meeting is necessary, because it was clear as recently as yesterday to our outside counsel, that DEA misconstrued portions of our counteroffer. The lack of real engagement by DEA continues to delay a resolution of this matter, costing AmerisourceBergen additional millions of dollars of expenses, lost business and reputational harm for no legitimate reason.

For the foregoing reasons, we seek your assistance in encouraging the DEA to engage in substantive face-to-face discussions on an expedited basis with AmerisourceBergen. We have attached a form of letter that we request that you consider sending to DEA Administrator Karen Tandy expressing your support for an expedited resolution of our matter. To be clear, we are not asking you to intercede on our behalf with respect to the substance of the DEA's action. We only ask that the DEA be encouraged to engage with us so that we may have the opportunity to resolve the matter before the end of June (more than two months from the time the action was first commenced).

We appreciate your consideration of our request.

Sincerely,



John G. Chou
Senior Vice President, General Counsel & Secretary

Attachments

Attachment 1

AmerisourceBergen's History of Cooperation with DEA

- Ongoing – AmerisourceBergen Drug Corporation (ABDC) personnel routinely assist DEA with investigations and verification of possible excessive or suspicious purchases. ABDC conducts daily reviews of orders by applying pre-determined dosage unit thresholds agreed upon with DEA. ABDC sends daily notices of potentially suspicious orders to DEA field offices and also compiles and submits monthly summaries for DEA.
- Ongoing – ABDC conducts internal investigations and continuous monitoring of customers placing potentially suspicious orders.
- Mid -1990s –ABDC developed a “suspicious order” monitoring program in conjunction with the DEA as part of a two-year project. Program implemented in 1998 with DEA approval. Program provided for daily and monthly reports of potentially suspicious purchases from each of the distribution centers that were monitored and shared with the DEA. DEA later asked that the Company provide reports only on monthly basis.
- 1999 to 2005 – ABDC assisted DEA in training DEA Diversion Investigators, including providing access to distribution facilities and presenting educational programs. ABDC also annually hosts DEA trainees from the Government facility at Quantico, Virginia, and ABDC regularly invites senior DEA enforcement officers to conduct compliance training for the company’s distribution center employees.
- 2002 – ABDC participated in an industry task force that developed Controlled Substance Ordering System (“CSOS”) software to support new regulations being promulgated by DEA.
- June 2003 – DEA awarded ABDC employees a Certificate of Appreciation for their involvement in an investigation of Highland Park Pharmacy.
- October 2004 – DEA provided ABDC an award “in recognition of AmerisourceBergen’s contribution to drug enforcement and to DEA’s training program.”
- 2004 to 2005 – ABDC participated with DEA and the Healthcare Distribution Management Association (“HIDMA”) in drafting and implementing rules for security procedures to prevent theft and diversion of List I chemicals.
- 2005 – ABDC cooperated in Operation Cyber-RX, investigation of Johar Saran drug trafficking organization. Joseph T. Rannazzisi, the Acting Deputy Assistant Administrator, DEA Office of Diversion Control, highlighted this investigation in his Congressional testimony on December 13, 2005, concerning illegal sales of pharmaceuticals over the internet.
- 2005 – ABDC collaborated with DEA to develop additional processes and controls to help identify potentially suspicious internet pharmacy orders, including developing with DEA and

implementing “best practices” for volume distributors of pharmaceuticals and controlled substances.

- November 2005 – ABDC investigated Armenia Pharmacy and Jen-Mar Pharmacy, requiring both to sign an agreement attesting either to no internet sales or to compliance with existing internet dispensing laws and requirements.
- November 2005 – Based on ABDC’s diversion compliance procedures, ABDC ceased sales to Universal Rx.
- December 2005 – ABDC implemented new policy and procedures that included requiring those customers that ABDC investigated and were found not to have any overt signs of diversion to fill out DEA-approved forms attesting to the nature of their sales before ABCD would allow them to continue doing business with the Company. ABDC sought and obtained DEA guidance for this program.
- December 2005 to April 2007 – ABDC conducted more than 100 investigations nationwide, cutting off shipments to companies that it could not verify as conducting fully legitimate operations. ABDC ceased shipments to several customers despite DEA advising the Company that sales could continue to those customers.
- February 2006 – Based on ABDC’s diversion compliance procedures, ABDC refused to open a new account for United Prescription.
- February 14, 2006 – DEA notified the Orlando distribution center that other distributors had recently ceased supplying several pharmacies, including four with which ABDC’s Orlando distribution center interacted: United Prescription, Universal Rx, Armenia Pharmacy, and Jen-Mar Pharmacy. Before receipt of DEA’s notice, ABDC had already cut off Universal Rx, refused to open an account for United Prescription, and required Armenia and Jen-Mar Pharmacies to sign agreements restricting internet sales.
- November 3, 2006 – After having identified Avec Pharmacy on suspicious order reports and conducting a site visit, ABDC stopped selling controlled substances to that pharmacy. ABDC provided courtesy notification to DEA.
- February 2, 2007 – DEA notifies ABDC that it revoked the registration of Avee Pharmacy, Inc.
- February 15, 2007 – ABDC terminated Grand Pharmacy as a customer after ABDC investigation. DEA revoked Grand’s registration on the same date.
- February 20, 2007 – ABDC cut off Medassist Rx, LLC following ABDC investigation.
- February 2007 – ABDC Orlando distribution center implemented more stringent limits on the number of dosage units of controlled substances in orders placed by customers serviced out of that distribution center. This new protocol increased the number of orders flagged by the

Company as suspicious and thus reported to DEA, resulting in 626 suspicious orders reported to DEA between March 15, 2007, and April 23, 2007.

- April 24, 2007 – DEA served Order to Show Cause and Immediate Suspension of Registration, dated April 19, 2007 (the “OSC”), requiring immediate suspension of Certificate of Registration, No. RA0210409, ABDC’s Orlando distribution center’s license to distribute controlled substances to its registered customers. OSC identifies ABDC shipments of alleged “suspicious orders” to four pharmacies: Avec Pharmacy, Grand Pharmacy, Medassist Rx, and Discount Mail Meds, LLC.
- April 24, 2007 – ABCD shut down Florida distribution center’s shipments of controlled substances and immediately suspended all shipments of controlled substances from all distribution centers to Discount Mail Meds, the only one of the four dispensing pharmacies named in the OSC to which ABDC had not already stopped shipment of controlled substances by the time the OSC was issued. ABDC also thoroughly examined all Florida accounts, implemented more stringent controls, and reported all potentially suspicious activity to the DEA.
- April 27, 2007 – DEA and ABDC entered Order of Special Dispensation to allow Orlando distribution center to continue shipping controlled substances to hospitals, clinics, Department of Defense facilities, pharmacies located within and exclusively servicing the aforementioned facilities, and to three additional designated facilities and their respective subsidiaries.
- Ongoing – ABDC has been working continuously with DEA to develop a new suspicious order monitoring system, including developing new parameters for computer monitoring of potentially “suspicious orders.”
- May 11, 2007 – ABDC closes several accounts serviced by Houston distribution center after conducting internal investigations.

DRAFT

June __, 2007

Honorable Karen Tandy

Administrator

Drug Enforcement Administration

600 Army Navy Drive

Arlington, VA 22202

Dear Administrator Tandy:

I am writing on behalf of AmerisourceBergen Drug Corporation in connection with the suspension of the registration of its Orlando distribution facility (the "Orlando Facility").

AmerisourceBergen is headquartered in Valley Forge, Pennsylvania and has substantial distribution facilities throughout California and elsewhere in the United States.

It is my understanding that the DEA registration of the Orlando Facility was suspended on April 24 due to compliance concerns raised by the DEA. I share the DEA's commitment to protecting the public safety by requiring high standards of operational oversight and compliance at pharmaceutical distribution facilities, especially those that are registered to distribute controlled substances. In addition, I support rigorous enforcement efforts in this area that reinforce these important priorities.

In meetings with AmerisourceBergen officials, I have been informed they are committing extensive resources to satisfying your demands expeditiously as outlined in a proposed settlement agreement between DEA and AmerisourceBergen and as outlined in various commitments tendered by AmerisourceBergen. Notwithstanding AmerisourceBergen's good faith efforts, I am advised that you have determined to defer reinstatement of the registration of the Orlando Facility until August 25, 2007, even if all demands of the DEA are met prior to that time. AmerisourceBergen officials have outlined to me the very severe daily economic consequences of the suspension. In the interest of fairness, I request that the DEA consider a more accelerated timetable for reinstatement. My hope is that the DEA can resolve this matter in a way that balances the public safety imperative against the economic hardship imposed on AmerisourceBergen of further delay in resolving this matter in an appropriate manner.

In any event, I request that the DEA respond promptly and affirmatively to AmerisourceBergen's ongoing requests for face-to-face negotiations in order to reach a settlement of this matter expeditiously. I understand that the last face-to-face meeting that AmerisourceBergen had with the DEA occurred in mid-May. I believe that it is in the public interest to resolve this matter as quickly as possible.

Thank you for your consideration of these requests and for your agency's diligent efforts to combat diversion of controlled substances.

Sincerely,

DRAFT

June __, 2007

Honorable Karen Tandy

Administrator

Drug Enforcement Administration

600 Army Navy Drive

Arlington, VA 22202

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